analysing the use of drug treatments;

identifying when only a certain proportion of the drug treatments remain;

submitting the recorded treatment information to a data centre once only the certain proportion of the drug treatments are identified as remaining;

analysing the recorded treatment information of the data centre according to a protocol in order to formulate a result which identifies whether certain specifications are satisfied, and where the result indicates that certain specifications have not been satisfied, referring the patient to a doctor.

Please amend claim 37 to recite as follows:

---

37. A method according to claim 31, further including the step of generating a repeat prescription order signal when it is identified that only a certain proportion of the drug treatment remains.

REMARKS

In the present Office Action, claims 1-38 were examined. Claims 1-38 are rejected, no claims are objected to, and no claims are allowed.

By this Amendment, claims 1, 19, 20, 22, 25-29, 31 and 37 have been amended, no claims have been canceled, and no claims have been added. Accordingly, claims 1-38 are presented for further examination. No new matter has been added. By this Amendment, claims 1-38 are believed to be in condition for allowance.

Rejections/Objections under 35 USC §112

The Examiner objected to the drawings as failing to comply with 37 CFR 1.84(p)(4). Specifically, the Examiner objected to the reference character "5" as referring to both a button and a data carrier. This objection is respectfully traversed in view of the changes to the specification.

Note that all references to numerical character 5 are now for a data carrier. A button is one preferred form of a data carrier.

The Examiner rejected claim 1-12 under 35 U.S.C. §112, second paragraph. Applicant respectfully traverses this rejection with respect to the claims as amended.

Specifically, the Examiner objected to the limitations "the drug delivery apparatus" in claim 1. This rejection is respectfully traversed by the above-noted amendment to claim 1. Also, the Examiner objected to the limitation "the repeat prescription re-ordering portion" in claim 28. This rejection is respectfully traversed by the above-noted amendment to claims 22 and 25-28.

Rejections under 35 USC §102

The Examiner rejected claim 1-8, 12-14, 16, 17 and 19-21 under 35 U.S.C. §102(b) as being anticipated by Wolf, et al. (U.S. Patent No. 5,505,195). Applicant respectfully traverses this rejection with respect to the claims as amended.

Wolf, et al. discloses various dry powder inhalation devices for delivering drugs to the respiratory systems of patients and which include a data logging system. Basically, Wolf, et al. counts the drug delivery events which occur. In addition, it refers to the recording of some of the characteristics of the treatment, for example whether or not the inhalation by the patient was sufficiently strong that a satisfactory treatment has taken place. All of this information which is recorded can then be downloaded and sent to a doctor or the like. It will be clear from a reading of the specification of Wolf, et. al., for example column 1 lines 13 to 19, lines 29 to 31, column 2 line 31, line 43, and line 51, that Wolf, et al. is interested only in recording, monitoring and analysing the patient's use of the inhalation devices. The Examiner refers in particular to Figure 6, in which the drug to be delivered to the patient is supplied in the form of a disc with eight blisters that are punctured by the inhalation device through which the patient inhales, drawing the contents of the punctured blister into his or her lungs. There are two different components here. Firstly, there is a drug delivery device from which the patient inhales, and secondly there is the disc containing eight blisters of the drug to be delivered. In Wolf, et al. in column 7 lines 56 to 58, it is clear that, once the eight blisters of a disc are used, a new disc is obtained and inserted into the device. Thus, once a patient has used up his supply of discs, he will obtain a new prescription for a further supply for use within the drug delivery device.

In contrast, the purpose of the present invention is to effect delivery of the correct amount of the drug by the delivery device and uses a date carrier to use drug information for use in the drug delivery device. Therefore, claim 1 of the present application is

distinguished over Wolf, et al. in two respects, firstly by the drug package including a data carrier. The drug package disclosed in Figure 6 of Wolf, et al. contains a plurality of drug blisters containing drugs for delivery to a patient, but does not disclose a data carrier. The data carrier is part of the inhalation device, and not part of the disc. Secondly, claim 1 makes it clear that the data carrier includes drug treatment information for use by a drug delivery apparatus, whereas Wolf, et al. only discloses the recordings of treatments. The key here is that the drug treatment information in the present invention is for use by the drug delivery apparatus in delivering the drug, perhaps in the appropriate amount, or at the appropriate time.

Regarding claim 6, Wolf, et al. does not disclose the transfer of treatment information to a drug delivery apparatus. In all examples given in Wolf, et al., the data recorded by the electronics within the housing 110 are merely recordings of what treatment has actually occurred, and the information is not transferred from the electronics to a data carrier. Therefore, claim 6 is clearly novel over Wolf, et al.. The same arguments can be used in support of the novelty of claim 7.

With regard to claim 13, Wolf, et al. does disclose a number of the features of this claim. However, it does not disclose an input for receiving treatment information for each treatment to be delivered to a patient and does not disclose the control of the amount of a drug delivered to a patient on the basis of the received treatment information. The devices in Wolf, et al. deliver a measured amount of a drug to a patient, and this measured amount is not varied. The treatment information of the present invention causes the delivery device to deliver the correct amount of the drug to a patient on the basis of this information. Wolf, et al. merely records details of each treatment. Therefore, claim 13 is novel over Wolf, et al.. The input is further defined in claim 14 as an electronic input (of the drug delivery apparatus) that receives the treatment information from the electronic data carrier. Wolf, et al. does not disclose the receiving of the treatment information by the drug delivery device from the data carrier. Wolf, et al. is concerned only with recording treatments dispensed by the apparatus.

With regard to claim 19, it is believed that the Examiner is interpreting the claim incorrectly. Claim 19 firstly is directed towards a data carrier for use with a drug delivery apparatus. Contrary to this in Wolf, et al., the electronic housing which records treatment information which has occurred forms part of the drug delivery apparatus, and is therefore

not "for use with" the drug delivery apparatus. In addition, claim 19 refers to a memory for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug. It is clear from this wording that the treatment information is for use by the drug delivery apparatus in delivering a specified drug, and is not concerned with the recording of treatment information. The fact that the data carrier in addition does record treatment information is irrelevant because it is not claimed in the independent claim. Further, any "memory" in Wolf, et al. is either part of the drug delivery apparatus, in which case there is no output for transmitting treatment information to the drug delivery apparatus, or it is not part of the drug delivery apparatus, in which case there is no output for transmitting treatment information to the drug delivery apparatus.

Please note that claim 19 has been amended to state that the memory is located within the electronic data carrier.

In claim 20, the invention is again distinguished over Wolf, et al. by the fact that the electronic data carrier contains treatment information relating to the specified drug, and in that the drug delivery apparatus delivers the specified drug in conformity with the treatment information. Nothing in Wolf, et al. seems to indicate that the collected information recording concerning treatment relates to the specified drug. In addition, nothing in Wolf, et al. discloses the use of treatment information in controlling a drug delivery apparatus to deliver a specified amount of a drug. Note the amendment to line 4 of claim 20. The phrase "the treatment information including information relating to the amount of the specified drug to be delivered to a person by the drug delivery apparatus," was added. This further distinguishes the invention from the prior art.

In claim 20, the data carrier includes an output for transmitting treatment information to the drug delivery apparatus before each treatment. No such feature is seen in Wolf, et al.. Where information is transmitted in Wolf, et al., it is being downloaded to a separate data processing computer where the treatments which have been carried out can be analysed.

In claim 21, it is not believed that Wolf, et al. discloses a method for operating a drug delivery apparatus by supplying a data carrier. The drug delivery apparatus in Wolf, et al. includes a memory, but it can not be said that a data carrier is "supplied". The novel feature of this claim relates to transmitting treatment information from the data carrier to the drug delivery apparatus rather than receiving information concerning a treatment from

the drug delivery apparatus to the memory in the electronic housing. The flow of data in the present invention is opposite in direction to that in Wolf, et al..

Rejections under 35 USC §103

The Examiner rejected claims 9-11 and 15 under 35 U.S.C. §103(a) as being obvious and unpatentable in view of Wolf, et al. et al., taken in view of Rode et al. (U.S. Patent No. 6,315,719). Applicant respectfully traverses this rejection with respect to the claims as amended and in view of the remarks above concerning the primary reference.

The Examiner also rejected claims 22 to 35 under 35 U.S.C. §103(a) as being obvious and unpatentable over Wolf, et al. et al., taken in view of Eigler et al. (U.S. Patent No. 6,328,699). Applicant respectfully traverses this rejection with respect to the claims as amended and in view of the remarks concerning the primary reference.

Accordingly, Applicant submits that none of the references, alone or in combination, anticipate or make obvious the invention as presently claimed and that the application is now in condition for allowance. Therefore, Applicant respectfully requests reconsideration and further examination of the application and the Examiner is respectfully requested to take such proper actions so that a patent will issue herefrom as soon as possible.

If the Examiner has any questions or believes that a discussion with Applicant's attorney would expedite prosecution, the Examiner is invited and encouraged to contact the undersigned at the telephone number below.

Please apply any credits or charge any deficiencies to our Deposit Account No. 23-1665.

Respectfully submitted,
Jonathan Stanley Harold
Denyer, et al.

Date: February 13, 2003
Reg. No. 27,096

Signature of Attorney
William A. Simons
WIGGIN & DANA LLP
One Century Tower
New Haven, CT 06508-1832
Telephone: (203) 498-[xxxx]
Facsimile: (203) 782-2889

\10706\45\381286.1

AMENDED SPECIFICATION PARAGRAPHS
SHOWING MARKED-UP CHANGES

Page 7, lines 194 to 199

Referring to Figure 1, a nebulizer 10 is shown including a body 1 and a mouthpiece 2 through which a patient breathes to receive an atomized drug during inhalation. In addition, the nebulizer 10 includesa display 3 for displaying information concerning the use of the machine and the treatment being delivered, and an input 4 in the form of a receptive region in which a data carrier 5 in the form of a button [5] may be placed in order to transmit information concerning the treatment into the device 10.

Page 7, lines 206 to 216

In this case, the [button] data carrier 5 includes a small microchip having a memory, to which is connected an aerial. The atomizer 10 includes a radio frequency transmitter connected to a further aerial for generating a radio frequency (RF) signal. When the [button] data carrier 5 is placed in the region 4, the aerial within the button receives the radio frequency signal and generates electric power to operate the microchip. The microchip is then caused to generate an additional RF signal through the aerial in the [button] data carrier 5 which contains treatment information. This is detected within the nebulizer 10, so that the nebulizer receives treatment information from the [button] data carrier 5. In addition, the nebulizer 10 can receive an additional RF signal by which information concerning actual treatments are downloaded into the [button's] data carrier's 5 memory so that the [button] data carrier 5 may store information concerning actual treatments which may be read and analysed later.

Page 7, lines 217 to 219

A suitable RF system which can be used is the HiTag made by Phillips, and includes a [button] data carrier which includes a memory for holding data, and a reader for reading information from the [button] data carrier and for writing data onto the [button] data carrier.

Page 7, lines 220 to 225

The body 1 of the drug delivery apparatus 10 includes a button holder 6 in the form of a wall spaced from the surface of the body 1 adjacent the input 4 to form a pouch in which the data carrier 5 will fit. In this case, the data carrier 5 can be left in the holder 6 for the duration of a treatment, or even for the entire time that the package of drug is in use. To minimize the possibility of loss of the [button] data carrier 5, the button holder 6 includes an interlock to prevent the [button] data carrier 5 from falling out.

AMENDED CLAIMS SHOWING MARKED-UP CHANGES

1. (amended) A drug package comprising:

a plurality of drug vials containing drugs for delivery to a patient in a drug delivery device; and

[a] an electronic data carrier including drug treatment information for use by the drug delivery [apparatus] device.

2. A drug package according to claim 1, wherein the data carrier is arranged to include at least one of the following items of treatment information:

a. the dose of drug to be delivered;

b. the identity of the drug which is to be delivered;

c. the expiry date of the drug to be delivered; and

d. the number of treatments available from the drug package.

3. A drug package according to claim 1, wherein the drug vials contain drugs adapted for delivery in air inhaled by a patient to their lungs.

4. A drug package according to claim 3, wherein the drug vials are arranged to be used in conjunction with a drug delivery device for delivering the drug in the inhaled airstream of a patient.

5. A drug package according to claim 1, wherein the data carrier is an electronic data carrier.

6. A drug package according to claim 1, wherein the data carrier is arranged to transfer treatment information to a drug delivery apparatus when it is moved to a receptive surface or region of the drug delivery apparatus.

7. A drug package according to claim 1, wherein the data carrier is arranged to supply drug treatment information to a drug delivery apparatus a number of times corresponding to the number of treatments available from the drug package, or to the number of vials included in the drug package.

8. A drug package according to claim 1, wherein a single data carrier is included which includes the drug treatment information for each drug vial.

9. A drug package according to claim 1, wherein the data carrier is a radio frequency device.

10. A drug package according to claim 9, wherein the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery apparatus.

11. A drug package according to claim 10, wherein the data carrier is arranged to generate a radio-frequency signal bearing the treatment information.

12. A drug package according to claim 1, wherein the data carrier includes a memory for recording information concerning treatments received from the drug delivery device.

13. A drug delivery apparatus comprising:

a delivery portion for delivering a drug to a patient;

an input for receiving treatment information for each treatment to be delivered to a patient; and

a delivery controller for controlling the amount of drug delivered to a patient on the basis of the received treatment information.

14. A drug delivery apparatus according to claim 13, wherein the input is an electronic input which receives the treatment information from an electronic data carrier.

15. A drug delivery apparatus according to claim 13, wherein the input is a radio frequency input which receives the treatment information from a data carrier at radio frequency.

16. A drug delivery apparatus according to claim 14, wherein the input is additionally arranged to transmit completed treatment information to the data carrier for recordal.

17. A drug delivery apparatus according to claim 13, wherein the drug delivery apparatus includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery.

18. A drug delivery apparatus according to claim 13, wherein the drug delivery apparatus is one of a pneumatic nebulizer, a piezo-electric nebulizer and an ultrasonic nebulizer.

19. (amended) An electronic data carrier for use with a drug delivery apparatus comprising a memory <u>located within the electronic data carrier</u> for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus.

20. (amended) A drug delivery system comprising:

a drug delivery apparatus for delivering a specified drug; and

an electronic data carrier containing treatment information relating to the specified drug, <u>the treatment information including information relating to the amount of</u>

the specified drug to be delivered to a person by the drug delivery apparatus, and the data carrier including an output for transmitting treatment information to the drug delivery apparatus before each treatment with the specified drug, whereby the drug delivery apparatus delivers the specified drug in conformity with the treatment information.

21. A method of operating a drug delivery apparatus comprising:

supplying a plurality of vials of a drug for use with the drug delivery apparatus;

supplying a data carrier including treatment information;

transmitting treatment information from the data carrier to the drug delivery apparatus;

placing an amount of the drug from a vial in the drug delivery apparatus; and

delivery the drug in accordance with the treatment information from the data carrier.

22. (amended) A drug delivery device comprising:

(i) a delivery portion for delivering a drug to a patient;

a drug use analyser which records the use of the drug over a number of treatments as recorded treatment information, which analyses to amount of a drug delivered over a number of treatments and which identifies when only a certain proportion of the prescribed drug remains; and

a repeat prescription ordering portion which operates to [electronically order a repeat prescription once the drug use analyser identifies that less than the certain proportion of the prescribed drug remains] submit the recorded treatment information to a data centre once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data centre analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient.

23. A drug delivery device according to claim 22, wherein the repeat prescribed ordering portion includes a modem which automatically connects to a telephone system to electronically order a repeat prescription.

24. A drug delivery device according to claim 22, wherein the repeat prescription ordering portion includes a connection to an electronic network through which the repeat prescription is ordered.

25. (amended) A drug delivery device according to [any one of claims] claim 22, wherein the drug use analyser includes a counter for counting the number of drug treatments delivered.

26.(amended) A drug delivery device according to claim 25, wherein the drug [use] analyser includes a memory for holding the total number of drug treatments that are possible from an existing course of drug treatments.

27. (amended) A drug delivery device according to claim 26, wherein the drug use analyser includes a comparitor which compares the number of drug treatments that are possible from the memory with the number of drug treatments delivered from the counter, and generates a [re-order signed] report prescription order signal when only a certain proportion of the prescribed drug remains.

28.(amended) A drug delivery device according to claim 27, wherein the repeat prescription re-ordering portion orders a repeat prescription once it received a [re-order signed] repeat prescription order signal from the drug use analyser.

29. (amended) A drug delivery device according to any one of claim 22, wherein the drug use analyser includes a data carrier, including drug treatment information including the total number of drug treatments that are possible from an existing course of drug treatments.

30. A drug delivery device according to claim 29, wherein the memory for holding the total number of drug treatments is located in the data carrier.

31. (amended) A method of prescribing a drug, comprising:

supplying a patient with a course of a number of drug treatments for administering using a drug delivery device;

recording the use of the drug treatments; [analyzing] the use of the drug treatments;

identifying when only a certain proportion of the drug treatments remain; and

[electronically ordering a repeat prescription once it has been identified that only a certain proportion of the drug treatments remain] submitting the recorded treatment information to a data centre once only the certain proportion of the drug treatments are identified as remaining;

analysing the recorded treatment information of the data centre according to a protocol in order to formulate a result which identifies whether certain specifications are satisfied, and where the result indicates that certain specifications have not been satisfied, referring the patient to a doctor.

32. A method according to claim 31, further comprising:

issuing a course of drug treatments or a prescription for the course of treatments in response to the electronic order.

33. A method according to claim 31, wherein the electronic ordering is done via a modem connection to a telephone line.

34. A method according to claim 31, wherein the electronic ordering is done via a connection to an electronic network.

35. A method according to claim 31, wherein the analysing of the use of the drug treatments includes counting the number of drug treatments delivered.

36. A method according to claim 35, wherein the analysing includes the comparing of the number of drug treatments delivered with the total number of treatments supplied.

37. (amended) A method according to claim 31, further including the step of generating a [re-order] repeat prescription order signal when it is identified that only a certain proportion of the drug treatments remain.

38. A method according to claim 31, further comprising the supply of a data carrier with the course of a number of drug treatments, the data carrier bearing drug treatment information including the total number of drug treatments that are possible from the existing course of drug treatments.